UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

March 22, 2001

MEMORANDUM

Subject: Acute Toxicity Review for EPA Reg. No.: 10324-107 / Maquat MQ2525M-200

DP Barcode: D272187
Case No: 068945

To: Velma Noble, PM 31 / *Tracy Lantz*
Regulatory Management Branch
Antimicrobials Division (7510C)

From: Ian Blackwell, Biologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Through: Karen Hicks, Team Leader
Chemistry and Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

3/22/01

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: Mason Chemical Co.

FORMULATION FROM LABEL:

Active Ingredient(s):	% by wt.
n-Alkyl Dimethyl Benzyl Ammonium Chloride	0.011
n-Alkyl Dimethl Ethylbenzyl Ammonium Chloride	0.011
Other Ingredient(s):	99.978
Total:	100.000%

BACKGROUND: The Mason Chemical Company has submitted a set of four acute toxicity/ irritation studies in support of their product "Maquat MQ2525M-200". These studies were conducted by Tox Monitor Laboratories and reviewed by the EPA contractor Oak Ridge Laboratories. The MRID Numbers are 453014-01 through 453014-04.

No acute inhalation toxicity or dermal sensitization studies were provided for this submission. The registrant reports that he had to submit the four submitted studies to the California Department of Pesticide Regulation. All acute toxicity studies conducted on an EPA registered product must be submitted to the Agency. The registrant would like the acute inhalation toxicity and dermal sensitization studies supported by the data originally cited for this product. The acute toxicity requirements for this product were originally supported by the cite-all method.

RECOMMENDATIONS: PSB findings are:

1. The acute oral toxicity, acute dermal toxicity, primary eye irritation and primary skin irritation studies are acceptable.

2. PSB could not locate any acute toxicity data or citations to be used to support the acute inhalation toxicity or dermal sensitization studies. Therefore, the only source of information was the 9/13/200 product label. Thus, the toxicity profiles for the acute inhalation toxicity and dermal sensitization studies are derived from Maquat 10 label dated 9/13/2000. It would be preferable to have actual acute toxicity data, but this is currently all that is available.

The acute toxicity profile for Reg. No. 10324-107 is currently:

acute oral toxicity	IV	acceptable
acute dermal toxicity	III	acceptable
acute inhalation toxicity	IV	from 9/13/00 label
primary eye irritation	IV	acceptable
primary skin irritation	IV	acceptable
dermal sensitization	nonsensitizer	from 9/13/00 label

LABELING:

ID #: 010324-00107 MAQUAT MQ2525M-200

SIGNAL WORD: CAUTION

PRECAUTIONARY STATEMENTS:

Harmful if absorbed through skin. Avoid contact with eyes, skin or clothing. Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.

STATEMENT OF PRACTICAL TREATMENT (SOPT):

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

DATA EVALUATION REPORT

N-ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (MAQUAT MQ 2525M-200)

STUDY TYPE: ACUTE ORAL TOXICITY - RAT [870.1100 (81-1)]MRID 45301401

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K263

Primary Reviewer:
Susan Chang, M.S. Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T. Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A. Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

Oak Ridge National Laboratory Managed and Operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Reviewer: Ian Blackwell, M.S. Date 5/22/1

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. , Date _____
Antimicrobials Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Acute Oral Toxicity - Rat [OPPTS 870.1100 (§81-1)]

DP BARCODE: D272187 SUBMISSION CODE: S591523
P.C. CODE: 169159 CASE NO.: 068945

TEST MATERIAL: Maquat MQ 2525M-200, Lot No. MR-II-49

SYNONYMS: not reported

CITATION: Kukulinski, M. (2000) Acute oral toxicity study of Maquat MQ 2525M-200, Lot No. MR-II-49. Tox Monitor Laboratories, Inc., 33 West Chicago Avenue, Oak Park, IL 60302. Laboratory project identification 00-113-3, October 24, 2000. MRID 45301401. Unpublished.

SPONSOR: Mason Chemical Company, 721 West Algonquin Road, Arlington Heights, IL 60005

EXECUTIVE SUMMARY: In an acute oral toxicity study (MRID 45301401) five male and five female fasted young adult Sprague-Dawley rats were given a single oral 5000 mg/kg dose of Maquat MQ 2525M-200, Lot No. MR-II-49 by gavage and observed for 14 days.

All rats survived, were normal, and had normal body weight gains during the study. No gross changes were observed at necropsy.

The oral LD_{50} for males, females, and combined was > 5000 mg/kg (Limit test).

Maquat MQ 2525M-200, Lot No. MR-II-49 is in TOXICITY CATEGORY IV based on the LD_{50}.

This acute oral study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute oral study [870.1100 (§81-1)] in the rat.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Maquat MQ 2525M-200, Lot No. MR-II-49

   Description: clear liquid
   Lot/Batch #: MR-II-49
   Composition: not reported

2. Vehicle and/or positive control

   None

3. Test animals

   Species: rat
   Strain: Sprague-Dawley derived
   Age and/or weight at dosing: young adult; males: 222-244 g, females: 201-219 g
   Source: Harlan Sprague Dawley, Indianapolis, IN
   Acclimation period: at least 5 days
   Diet: Purina Rat Chow, *ad libitum*
   Water: *ad libitum*
   Housing: individually in stainless steel cages
   Environmental conditions:
   Temperature: not reported
   Humidity: not reported
   Air changes: not reported
   Photoperiod: not reported

B. STUDY DESIGN AND METHODS

1. In life dates

   Start: October 10, 2000; end: October 24, 2000

2. Animal assignment and treatment

   Following an overnight fast, five rats/sex were given a single 5000 mg/kg dose of the test material by gavage (Table 1). The animals were observed frequently for clinical signs of toxicity on the day of dosing and once daily thereafter for 14 days. They were weighed prior to dosing and on study days 7, and 14. Gross necropsy was done on all rats.

TABLE 1. Doses, mortality/animals treated			
Dose (mg/kg)	Males	Females	Combined
5000	0/5	0/5	0/10

Data taken from Table 1, p. 12, MRID 45301401.

3. Statistics

Calculation of LD_{50} was not required.

II. RESULTS AND DISCUSSION

A. MORTALITY

Mortality is given in Table 1. None of the rats died during the study.

The oral LD_{50} for males, females, and combined was > 5000 mg/kg (Limit test).

This places Maquat MQ 2525M-200, Lot No. MR-II-49 in TOXICITY CATEGORY IV.

B. CLINICAL OBSERVATIONS

All rats were normal throughout the study.

C. BODY WEIGHT

All rats had normal body weight gains.

D. NECROPSY

No gross changes were observed.

E. DEFICIENCIES

The environmental conditions of the animal room were not reported. This would not affect the study results.

DATA EVALUATION RECORD

N-ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE
(MAQUAT MQ 2525M-200)

STUDY TYPE: ACUTE DERMAL TOXICITY - RABBIT [870.1200 (81-2)]
MRID 45301402

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K263

Primary Reviewer:
Susan Chang, M.S.

Signature: _____
Date: _____

SecondaryReviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

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Oak Ridge National Laboratory Managed and Operated by UT-Battelle, LLC., for the U.S. Department of Energy under Contract No. DE-AC05-00OR22725.

EPA Reviewer: Ian Blackwell, M.S. , Date 3/22/1

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. , Date
Antimicrobials Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Acute Dermal Toxicity - Rabbit [OPPTS 870.1200 (§81-2)]

DP BARCODE: D272187 SUBMISSION CODE: S591523
P.C. CODE: 169159 CASE NO.: 068945

TEST MATERIAL: Maquat MQ 2525M-200, Lot No. MR-II-49

SYNONYMS: not reported

CITATION: Kukulinski, M. (2000) Acute dermal toxicity study of Maquat MQ 2525M-200, Lot No. MR-II-49. Tox Monitor Laboratories, Inc., 33 West Chicago Avenue, Oak Park, IL 60302. Laboratory project identification 00-113-4, October 31, 2000. MRID 45301402. Unpublished.

SPONSOR: Mason Chemical Company, 721 West Algonquin Road, Arlington Heights, IL 60005

EXECUTIVE SUMMARY: In an acute dermal toxicity study (MRID 45301402) approximately 10% of the body surface area of five male and five female young adult New Zealand Albino rabbits was dermally exposed to 2000 mg/kg (Limit Test) Maquat MQ 2525M-200, Lot No. MR-II-49 for 24 hours. The animals were observed for 14 days.

None of the animals died during the study. All rabbits appeared normal and had normal body weight gains throughout the study. Erythema was present on all rabbits on day 1 with resolution by days 2 or 3. No gross changes were observed at necropsy.

The dermal LD_{50} for males, females, and combined was > 2000 mg/kg (Limit Test).

Maquat MQ 2525M-200, Lot No. MR-II-49 is in TOXICITY CATEGORY III based on the LD_{50}.

This acute dermal study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for an acute dermal study [870.1200 (§81-2)] in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Maquat MQ 2525M-200

   Description: clear liquid
   Lot/Batch #: MR-II-49
   Composition: not reported

2. Vehicle and/or positive control

   None

3. Test animals

   Species: rabbit
   Strain: New Zealand Albino
   Age and/or weight at dosing: young adult; males: 2.10-2.71 kg, females: 2.60-2.72 kg
   Source: Kuiper Rabbitry, Gary, IN
   Acclimation period: at least 4 days
   Diet: Purina Rabbit Chow, *ad libitum*
   Water: *ad libitum*
   Housing: individually in stainless steel cages
   Environmental conditions:
   Temperature: not reported
   Humidity: not reported
   Air changes: not reported
   Photoperiod: not reported

B. STUDY DESIGN AND METHODS

1. In life dates

   Start: October 17, 2000; end: October 31, 2000

2. Animal assignment and treatment

   The study was conducted as a limit test using five male and five female rabbits. The animals were given a single 2000 mg/kg dose of Maquat MQ 2525M-200, Lot No. MR-II-49 applied to a shaved dorsal and ventral area of approximately 10% of the body surface. The application site was covered with a gauze dressing. A sleeve of plastic sheeting was fitted over the trunk and secured with non-irritating tape. The covering was removed 24 hours later and the residual test material wiped off. The animals were observed for clinical signs of toxicity frequently on the day of treatment and daily thereafter for 14 days. They were weighed prior to test material application, and on study days 7 and 14. All rabbits were sacrificed and necropsied.

3. Statistics

Calculation of the dermal LD_{50} was not required.

II. RESULTS AND DISCUSSION

A. MORTALITY

None of the rabbits died during the study.

The dermal LD_{50} for males, females, and combined was > 2000 mg/kg (Limit test). This places Maquat MQ 2525M-200, Lot No. MR-II-49 in TOXICITY CATEGORY III.

B. CLINICAL OBSERVATIONS

All rabbits were normal throughout the study. Erythema was noted on all rabbits on day 1 with resolution on eight rabbits by day 2 and on two rabbits by day 3.

C. BODY WEIGHT

All animals had normal body weight gains.

D. NECROPSY

No gross changes were observed.

E. DEFICIENCIES

The environmental conditions of the animal room were not reported. These would not affect the study results.

DATA EVALUATION RECORD

N-ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE
(MAQUAT MQ 2525M-200)

STUDY TYPE: PRIMARY EYE IRRITATION - RABBIT [870.2400 (81-4)]
MRID 45301404

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
Action No. K263

Primary Reviewer:
Susan Chang, M.S. Signature: _____
Date: _____

Secondary Reviewers:
H. Tim Borges, M.T.(A.S.C.P.), Ph.D., D.A.B.T.
Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A. Signature: _____
Date: _____

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EPA Reviewer: Ian Blackwell, M.S. _____, Date 3/22/1

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. _____, Date _____

Antimicrobials Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Primary Eye Irritation - Rabbit [OPPTS 870.2400 (§81-4)]

DP BARCODE: D272187 SUBMISSION CODE: S591523

P.C. CODE: 169159 CASE NO.: 068945

TEST MATERIAL: Maquat MQ 2525M-200, Lot No. MR-II-49

SYNONYMS: not reported

CITATION: Kukulinski, M. (2000) Acute eye irritation study of Maquat MQ 2525M-200, Lot No. MR-II-49. Tox Monitor Laboratories, Inc., 33 West Chicago Avenue, Oak Park, IL 60302. Laboratory project identification 00-113-1, October 20, 2000. MRID 45301404. Unpublished.

SPONSOR: Mason Chemical Company, 721 West Algonquin Road, Arlington Heights, IL 60005

EXECUTIVE SUMMARY: In a primary eye irritation study (MRID 45301404) 0.1 mL of Maquat MQ 2525M-200, Lot No. MR-II-49 was instilled into the conjunctival sac of one eye of six adult male New Zealand white rabbits. The contralateral eye of all rabbits served as the control. The eyes were scored for ocular irritation according to the Draize method 1, 24, 48, and 72 hours after instillation.

Corneal opacity and iritis were not found on any rabbit. The test material did not induce any positive conjunctival irritation. The highest maximum mean total score was 3.3 recorded 1 hour after test material instillation.

In this study, Maquat MQ 2525M-200, Lot No. MR-II-49 was minimally irritating and is in TOXICITY CATEGORY IV for primary eye irritation.

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a primary eye irritation study [870.2400 (§81-4)] in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Maquat MQ 2525M-200

Description: clear liquid
Lot/Batch #: MR-II-49
Composition: not reported

2. Vehicle

None

3. Test animals

Species: rabbit
Strain: New Zealand white
Age and weight at dosing: 8-10 weeks; males: 2.01-2.52 kg
Source: Kuiper Rabbitry, Gary, IN
Acclimation period: at least 5 days
Diet: Purina Rabbit Chow, ad libitum
Water: *ad libitum*
Housing: individually in stainless steel cages
Environmental conditions:
Temperature: not reported
Humidity: not reported
Air changes: not reported
Photoperiod: not reported

B. STUDY DESIGN AND METHODS

1. In life dates

Start: October 17, 2000; end: October 20, 2000

2. Animal assignment and treatment

The test material (0.1 mL) was instilled into the conjunctival sac of one eye of six male rabbits and the eye lids held together for approximately 1 second. The contralateral eye of all rabbits served as the control. The animals were scored for ocular irritation 1, 24, 48, and 72 hours after instillation according to the Draize method.

II. RESULTS AND DISCUSSION

A. Corneal opacity and iritis were not found on any rabbit. The test material did not induce any positive conjunctival irritation (score > 1). All rabbits had conjunctival

irritation (score 1) one hour after test material instillation with resolution on 4/6 rabbits by 24 hours and on 2/6 rabbits by 48 hours. The highest maximum mean total score was 3.3 recorded 1 hour after test material instillation.

This classifies the test material as minimally irritating. Maquat MQ 2525M-200, Lot No. MR-II-49 is in TOXICITY CATEGORY IV.

B. DEFICIENCIES

The environmental conditions of the animal room were not reported. These would not affect the study results.

DATA EVALUATION REPORT

N-ALKYL DIMETHYL BENZYL AMMONIUM CHLORIDE (MAQUAT MQ 2525M-200)

STUDY TYPE: PRIMARY DERMAL IRRITATION - RABBIT [870.2500 (81-5)] MRID 45301403

Prepared for
Antimicrobials Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
1921 Jefferson Davis Highway
Arlington, VA 22202

Prepared by
Chemical Hazard Evaluation Group
Toxicology and Risk Analysis Section
Life Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37831
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Quality Assurance:
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EPA Reviewer: Ian Blackwell, M.S. _____, Date 3/22/1

EPA Work Assignment Manager: Bonaventure Akinlosotu, Ph.D. _____, Date _____
Antimicrobials Division (9510C)

DATA EVALUATION RECORD

STUDY TYPE: Primary Dermal Irritation - Rabbit [OPPTS 870.2500 (§81-5)]

DP BARCODE: D272187 SUBMISSION CODE: S591523
P.C. CODE: 169159 CASE NO.: 068945

TEST MATERIAL: Maquat MQ 2525M-200, Lot No. MR-II-49

SYNONYMS: not reported

CITATION: Kukulinski, M. (2000) Acute dermal irritation study of Maquat MQ 2525M-200, Lot No. MR-II-49. Tox Monitor Laboratories, Inc., 33 West Chicago Avenue, Oak Park, IL 60302. Laboratory project identification 00-113-2, October 20, 2000. MRID 45301403. Unpublished.

SPONSOR: Mason Chemical Company, 721 West Algonquin Road, Arlington Heights, IL 60005

EXECUTIVE SUMMARY: In a primary dermal irritation study (MRID 45301403) six male adult New Zealand white rabbits were dermally exposed to 0.5 mL Maquat MQ 2525M-200, Lot No. MR-II-49 for 4 hours. The animals were observed for 72 hours. Irritation was scored by the method of Draize.

Very slight erythema was noted on 2/6 rabbits 30 minutes following patch removal with resolution by 24 hours. Very slight erythema was noted on 1/6 rabbits 24 hours after treatment with resolution by 48 hours. The primary irritation index was 0.13.

In this study, Maquat MQ 2525M-200, Lot No. MR-II-49 was essentially non-irritating and is in TOXICITY CATEGORY IV for primary dermal irritation.

This study is classified as **Acceptable/Guideline** and satisfies the subdivision F guideline requirements for a primary dermal irritation study [870.2500 (§81-5)] in the rabbit.

COMPLIANCE: Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material: Maquat MQ 2525M-200

   Description: clear liquid
   Lot/Batch #: MR-II-49
   Composition: not reported

2. Vehicle

   None

3. Test animals

   Species: rabbit
   Strain: New Zealand white
   Age and weight at dosing: approximately 8-10 weeks; males: 2.25-2.53 kg
   Source: Kuiper Rabbitry, Gary, IN
   Acclimation period: at least 5 days
   Diet: Purina Rabbit Chow, *ad libitum*
   Water: *ad libitum*
   Housing: individually in stainless steel cages
   Environmental conditions:
   Temperature: not reported
   Humidity: not reported
   Air changes: not reported
   Photoperiod: not reported

B. STUDY DESIGN AND METHODS

1. In life dates

   Start: October 17, 2000; end: October 20, 2000

2. Animal assignment and treatment

   Six male animals were given a single 0.5 mL dose of Maquat MQ 2525M-200, Lot No. MR-II-49 applied to an approximately 6 cm^2 clipped site on the side of the animal. The application site was covered with a gauze patch, held in place with non-irritating tape, and wrapped with semi-occlusive plastic overwrap. After 4 hours, the dressing and the excess test material were removed. The site was scored for erythema and edema according to the Draize method approximately 30 minutes after patch removal and 24, 48, and 72 hours after treatment.

II. RESULTS AND DISCUSSION

A. Very slight erythema was noted on 2/6 rabbits 30 minutes following patch removal with resolution by 24 hours. Very slight erythema was noted on 1/6 rabbits 24 hours after treatment with resolution by 48 hours. The primary irritation index was 0.13.

Maquat MQ 2525M-200, Lot No. MR-II-49 was essentially non-irritating and is in TOXICITY CATEGORY IV.

B. DEFICIENCIES

The environmental conditions of the animal room were not reported. These would not affect the study results.